

## REMARKS

Claims 1-49, and 51-82 constitute the pending claims in the present application. Claims 48-55 were initially elected with traverse. Claims 1-47 and 56-79 are withdrawn from consideration as being drawn to a non-elected invention. Applicants will cancel these claims upon indication of allowable subject matter in the elected invention. Claim 50 has been canceled without prejudice. Claims 48, 49, and 51 have been amended. No new matter is being introduced. Support for the claim amendments and the new claims is found throughout the specification. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

### Objection withdrawal

Applicants note that the objection to the specification is withdrawn in view of the amendments to the specification.

### Claim rejections under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph

Claims 48-55 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection to the extent it is maintained over the claims as amended.

Specifically, the Office Action asserts that the recitations “in a display mode” and “in a secretion mode” are not positive characterizations of the product vector. In particular, the term “mode” is allegedly unclear. Applicants contend that the Merriam-Webster Dictionary clearly defines “mode” as “a form or manner of expression.” Applicants maintain that, when read in light of the specification, the phrases “in a display mode” and “in a secretion mode” are not unclear, and serve to illuminate the features of the vector being claimed (see e.g., pages 14-30; and pages 30-43).

Nevertheless, solely to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended independent claim 48 to more particularly point out the features of the claimed vector. Specifically, the phrase “in a display mode” is changed to “in a prokaryotic cell,” while the phrase “in a secretion mode” is changed to “in a eukaryotic cell.” Applicants also amended dependent claims 49 and 51 to reflect the features of the claimed vectors. These claim amendments are fully supported throughout the specification (e.g., the paragraph bridging pages 29 and 30; pages 59-60). Applicants submit that a skilled artisan, in view of the claim language and the teaching of the specification, would have no difficulty in determining the metes and bounds of the claimed subject matter. Accordingly, claim 48 is both clear and definite to one skilled in the art. Reconsideration and withdrawal of rejections under 35 U.S.C. § 112, second paragraph, are respectfully requested.

#### Claim rejections under 35 U.S.C. § 102

Claims 48-55 stand rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by Larocca et al. (U.S. Pat. No. 6,054,312). Applicants respectfully traverse this rejection to the extent it is maintained over the claims as amended.

Although for the reasons already made of record, Applicants maintain that these claims are not anticipated by Larocca et al., without amendment, Applicants have amended independent claim 48 solely to expedite prosecution.

The standard for anticipating a claim is clearly outlined in MPEP 2131, and this standard is further supported by the Courts. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1978). “The identical invention must be shown in as complete detail as is contained in the claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Applicants contend that Larocca et al. fail to satisfy this criterion for anticipating the present invention. Larocca et al. disclose that filamentous phage particles displaying a ligand on their surface are used to deliver a therapeutic gene to a cell. Larocca et al. specifically teach

delivering a fusion protein to a cell. For example, “within the context of this invention, the ligand is conjugated to a protein of a bacteriophage, either as a fusion protein or through chemical conjugation, and is used to deliver a nucleic acid payload (i.e., therapeutic gene) to a cell” (column 10, lines 1-5). Larocca et al. provide a working example showing a vector comprising a chimeric gene comprising FGF2-3 fused to a gene encoding the coat protein III or VIII (see column 37, line 65 to column 38, line 23).

In contrast, claim 48 as amended, recites a vector comprising a chimeric gene for a chimeric protein, wherein the vector performs differently in a prokaryotic cell as compared to in a eukaryotic cell. The claim clearly points out the feature of the vector: in a prokaryotic cell, the chimeric gene is expressed as a fusion protein including the test peptide and the surface protein such that the test peptide can be displayed on the surface of a display packages, whereas in a eukaryotic cell, the test peptide is expressed without the surface protein as a result of the coding sequence for the surface protein being removed by RNA splicing.

Applicants submit that Larocca et al. neither disclose nor teach a vector that has these distinct functions in a prokaryotic and a eukaryotic cell. Clearly, Larocca et al. fail to teach that in a eukaryotic cell, the ligand is expressed without the surface protein as a result of the coding sequence for the surface protein being removed by RNA splicing. In fact, Larocca et al. teach expression of a fusion protein between the ligand and a surface protein only. Accordingly, Larocca et al. do not apparently teach the features of the claimed vector, nor any advantage in or motivation to obtaining free proteins (i.e., without being fused to the surface protein) in their invention.

Additionally, the present claims further require that RNA splice sites in the vector flank the coding sequence for the surface protein such that the test peptide expressed in a prokaryotic cell differs from the test peptide expressed in a eukaryotic cell. The teachings of Larocca et al. are completely silent on this issue. One of skill in the art has no way of knowing whether the RNA splice sites of Larocca et al. flank the coding sequence of the test peptide, or whether they flank other critical DNA elements such as a promoter.

The Examiner asserts that "Larocca would have inherently known such fact in the art of RNA splicing sites. Since Larocca is able to display and secrete the test peptide indicates that the RNA splices the sites that flanks the test peptide to enable its secretion." However, there is no indication that Larocca contemplated a vector that behaves in a eukaryotic cell as presently claimed. Applicants respectfully remind the Examiner that MPEP 2112 clearly points out that "[T]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic."

Accordingly, Applicants respectfully submit that Larocca et al. fail to teach or suggest all the features of the present claims and thus fail to anticipate the claimed subject matter. Reconsideration and withdrawal of this rejection are respectfully requested.

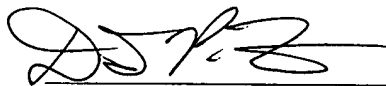
### **CONCLUSION**

The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

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Respectfully Submitted,



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